(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 0 720 454 B1

(12) EUROPEAN PATENT SPECIFICATION

(45) Date of publication and mention of the grant of the patent:
24.11.1999 Bulletin 1999/47

(21) Application number: **94927880.8**

(22) Date of filing: **05.08.1994**

(51) Int. Cl.[6]: **A61F 2/02**, A61L 27/00, A61C 8/00

(86) International application number:
PCT/SE94/00724

(87) International publication number:
WO 95/09583 (13.04.1995 Gazette 1995/16)

(54) AN IMPLANT

IMPLANTAT

IMPLANT

(84) Designated Contracting States:
AT BE CH DE DK ES FR GB IT LI NL

(30) Priority: **01.10.1993 SE 9303206**

(43) Date of publication of application:
10.07.1996 Bulletin 1996/28

(73) Proprietor: **LUCOCER AKTIEBOLAG**
S-263 52 Höganäs (SE)

(72) Inventors:
- **JOHANSSON, Thomas**
S-263 52 Höganäs (SE)
- **HARRYSSON, Ralph**
S-951 63 Lulea (SE)
- **HERMANSSON, Leif**
S-754 26 Uppsala (SE)

(74) Representative: **Hynell, Magnus**
Hynell Patenttjänst AB,
Patron Carls väg 2
683 40 Hagfors/Uddeholm (SE)

(56) References cited:

WO-A-92/21302	WO-A-93/13815
US-A- 4 865 603	US-A- 5 222 983

EP 0 720 454 B1

Description

TECHNICAL FIELD

[0001] The present invention generally relates to the field of medical applications, more particularly to the field of implantology, and concerns an implant intended to be fixed through contact with new grown bone tissue, which implant at least partly consists of a dense material having, at least within a portion of its surface, surface pores, which cover 5-40 % of said surface portion which shall constitute a contact surface for new grown bone tissue.

[0002] US-A-5222 983 discloses an implant having surface pores showing all the features of the preamble of Claim 1.

BACKGROUND ART

[0003] When using supporting implants it is important that the implant material has a high strength and that a sufficiently high resistance to shearing forces is developed between the implant and new grown bone tissue; the latter feature being important for the achievement of a good retention. A high strength of implant materials can be achieved by using dense materials having an inherent high strength, such as conventional construction materials, for example stainless steel, cobalt-chromium alloys, titanium and titanium alloys, ceramic materials or polymers or materials with controlled defects, including pores. For the fixation of implants it is known in the art to utilize a topographic surface or pores, wherein retention is achieved through the establishment of a good contact between the implant and new grown bone tissue.

[0004] In the Swedish patent No. 468 502, certain aspects relating in the first place to the pore size distribution in porous implant materials have been disclosed. Specific and complex pore size distributions in this respect have been found possible to use for depositing bone growth promoting substances and in order to stimulate a good bone ingrowth in larger pores.

[0005] In a Swedish patent application No. 9200072-8 is described how the micro porosity of an implant can be utilized for the deposition of one or more bone growth promoting substances by means of carriers prior to implantation. By filling the pores to a different degree with carriers having a poor solubility, and with appropriate active agents, the formation of pores for bone ingrowth and, for release of active substances can be controlled in order to achieve an optimal ingrowth.

BRIEF DISCLOSURE OF THE INVENTION

[0006] It is an object of the invention to provide an implant material having an improved retention. This is achieved, according to the invention, therein that close to at least a substantial fraction of all of said surface pores there is at least one elevation which extends over the implant surface surrounding the brim of the pore. The elevation or the elevations is/are not bound to any specific topography, but preferably they should have the shape of one or more ridges which partly or completely surround the pore. In order that the desired improvement of the retention shall be achieved, at least any elevation around the pore should have an altitude amounting to at least 1 μm, suitably at least 5 μm, over the surrounding material surface. The height is limited in first place by conditions which have to do with production technology. Therefore the maximal altitude is not more than 20 μm.

[0007] The elevation or elevations around the surface pores, according to the invention can be produced according to various techniques. In those cases when the implant material at least within the portion in question of the surface of the implant consists of a material having a good ductility, such as most metals (also alloys are included in the concept of metals), the surface pores are suitably produced through thermal etching or through supersonic working. Depending on the curvature of the implant, supersonic working can be chosen, which is to be preferred on comparatively flat regions, or thermal etching for more curved parts. For the latter case, more particularly laser should be used. Preferably there is used a laser of the carbon dioxide type; YAG laser, or Excimer laser. By proper arrangement of the apparatus a desired geometry and pattern can be achieved, and by proper adjustment of the supplied power, the elevations around the pore edge can be created through crater formation at the establishment of the pore in those cases when the material is sufficiently ductile. Which materials that are sufficiently ductile and how the pore formation shall be performed in order to create the said crater formation and hence the desired elevations can be determined through empirical experiments.

[0008] In those cases when the material within the surface portion in question has so poor ductility that any elevations can not be formed, such as craters, at the establishment of the pore by means of laser or the like, which is normally the case e.g. for ceramics, the desired elevations around the pore instead can be established by removing material in a region around the brim portion of the pore, so that the brim portion will remain as an elevation over the surrounding surface.

[0009] Generally it can be said that through the invention there is achieved an improved balance between the reten-

tion and the strength of the implant material. Through optimized ingrowth of bone tissue in surface pores having beads (elevations) according to the invention, the resistance against shear forces between implant and new grown bone can be increased from about 3-4 MPa for cylinders without surface pores to more than about 8 MPa for cylinders having surface pores.

[0010] Further characteristic features and aspects of the invention will be apparent from the following embodiments and from the appending claims.

BRIEF DESCRIPTION OF DRAWINGS

[0011] In the following description, reference will be made to the accompanying drawings, in which

Fig. 1A-C	illustrate examples of some various patterns which the surface pores can form on the implant surface,
Fig. 2	shows some surface pores in Fig. 1A at a larger scale,
Fig. 3	schematically shows a section through a surface pore along a line III-III in Fig. 2, and
Fig. 4	shows a section through an embodiment having a theoretically ideal design with inclined surface pores.

DETAILED DESCRIPTION OF THE INVENTION

[0012] In Fig. 1A a portion of an implant surface 1 has surface pores 2 arranged in a square pattern. Fig. 1B shows a portion of an implant surface 1 having surface pores 2 arranged in a hexagonal or rhombic pattern. Fig. 1C shows a portion of an implant surface 1 having surface pores 2 arranged in a spiral pattern.

[0013] In Fig. 2 there is shown a number of surface pores 2 having elevations 3 extending more or less continuously around the edge of the pore. The elevations 3 have the form of crater formations, which may arise at the formation of the surface pores through working by means of laser if such parameters as supplied power, time etc. are properly set.

[0014] Fig. 3 illustrates how a pore 2 and the region adjacent to the pore may look according to the invention in a typical case. In the drawing, the diameter of the pore 2 is designated D and its depth is designated d. The maximal height of the elevation or the elevations 3 over the material surface 4 surrounding the edge of the pore 2 is designated h. The ratio between the diameter and the depth of the surface pores, D/d, and the height h of the elevation 3 are important for the retention. Thus D/d should lie within the range 0.1-10, preferably in the range 0.5-2. The height h under these conditions should be at least 1 μm, preferably at least 5 μm, while the maximal height h may be up to 20 μm. The mean diameter of the surface pores 2 should be between 100-200 μm, the surface pore depth should be between 50-200 μm, and the distance between adjacent surface pores should be between 50-200 μm.

[0015] Fig. 4 shows surface pores 2' having inclined pore walls 5, which in combination with the elevations 3 further enhances the retention. The inclination of the pore walls 5 may amount to about 30° relative to the normal directions of the surface pore openings.

EXAMPLES

[0016] 24 cylinders of a completely dense, i.e. without any pores interior of the surface, C P titanium having a diameter of 2.8 mm and a length of 6 mm were implanted in the femure of rabbits for 4 and 12 weeks, respectively. The rabbits were of type New Zealand White having a weight of about 4 kg. Half of the cylinders had pores, which were thermally etched by means of laser having the following apparatus parameters, wherein surface pores were achieved having a mean diameter of about 150 μm and a depth of the same order. Ridge shaped elevations were formed around the opening of the pores through the laser treatment, the ridges having a maximal height over the surrounding material surface of about 5 μm. The mean distance between the surface pores was about 120 μm.

Laser type	YAG The laser beam was moved to and fro over the cylinder surface in the axial direction, the cylinder being turned between each change of movement direction
Rate of movement:	630 mm/min
Turning angle	appr 14°
Pulse frequency	30 Hz
Pulse width	0.13 ms
Lamp voltage	600 V
Pulse power	0.6 J
Beam path aperture	3.0 mm
Focal point	4.2 mm over the material surface

[0017] Prior to sterilization the implant samples were cleaned ultrasonically in HCl-solution for 1 h, whereafter the samples were stored in 1 M HCl-solution for 14 h. The samples finally were washed, firstly in di-ionized water and 70 % alcohol and secondly in destillated water. The samples were sealed in special bags and autoclaved for 20 min. In the femure (a leg) of each rabbit three holes were drilled by means of a special drilling device at a distance of about 10 mm from each other and at a distance from the growth zone in cortical bone under a heavy saline flow in order to promote efficient cooling. A low drilling pressure was applied. The drilling produced holes having appr 0.1 mm play for the cylinder samples. After the period of implantation, the animals were put to death by an overdose of Mebumal, and were prepared for so called push-out tests and for histological evaluation.

[0018] A 10 mm long bone section with the implant in the centre thereof was prepared from the femure. The bone sections were cut longitudinally in order to make available the part of the implant facing the bone marrow. The prepared bone was kept in 0.9 % NaCl solution without any fixation. Bone with cylinder was placed in a push-out fixture by means of a dental cement. The maximal force required for loosing the implant from the bone was detected by means of a universal instrument for measurement of strength (Alwetron) having a loading rate of 0.5 mm/min. The shear force between implant and bone was calculated through measured power divided by the present contact surface between bone and implant. The results are given in Table 1.

Table 1

Shear power between implant and bone							
U = without surface pores M = with surface pores							
Animal No	Implant 1 MPa	Implant 2 MPa	Implant 3 MPa	Animal No	Implant 1 MPa	Implant 2 MPa	Implant 3 MPa
	6 weeks				12 weeks		
1	U 2.1	M 8.3	M 11.4	5	U 3.7	M 15.8	M 17.2
2	U 1.6	M 7.9	M 8.9	6	U 4.3	M 14.9	M 20.1
3	U 1.9	U 2.3	M 7.7	7	U 3.3	U 4.7	M 18.8
4	U 2.2	U 0.8	M 10.1	8	U 4.2	U 3.9	M 16.4

Claims

1. An implant intended to be fixed through contact with new grown bone tissue, which implant at least partly consists of a dense material having, at least within a portion (1) of its surface, surface pores (2), which cover 5-40 % of said surface portion (1), which shall constitute a contact surface for new grown bone tissue, said pores having a diameter (D) which amounts to between 100 and 200 μm and a pore depth (d) amounting to between 50 and 200 μm, wherein the distance between adjacent pores is between 50 and 200 μm, and wherein close to at least a substantial fraction of said surface pores there is at least one elevation (3) which extends over the implant surface surrounding the brim of the pore, **characterized** in that the maximal height (h) of the elevation over the material surface (4) amounts to at least 1 μm but not more than 20 μm.

2. An implant according to claim 1, wherein the elevation or the elevations consist of a ridge or ridges completely or partially surrounding the pore.

3. An implant according to claim 1 or 2, wherein the maximal height of the elevation over the implant surface (4) amounts to at least 5 μm.

4. An implant according to any of claims 1-3, wherein at least that part of the implant surface which comprises the portion (1) having said surface pores consists of a metal, of a polymeric, or of a composite material substantially consisting of a metal or of a polymer.

5. An implant according to any of claims 1-3, wherein at least that part of the implant which comprises the portion (1) having said surface pores consists of a ceramic or of a composite material substantially consisting of a ceramic material.

6. An implant according to any of claims 1-5, wherein the surface pores as well as the elevations which completely or

partly surround the surface pores are produced through laser treatment of the implant material.

Patentansprüche

1. Implantat, das durch den Kontakt mit neu gewachsenem Knochengewebe gehalten werden soll, wobei das Implantat zumindestens teilweise aus einem dichten Material besteht, das mindestens in einem Teil (1) seiner Oberfläche Oberflächenporen (2) aufweist, die 5-40 % des Oberflächenteils (1) bedecken, der eine Kontaktoberfläche für neu gewachsenes Knochengewebe bilden soll, wobei die Poren einen Durchmesser (D) aufweisen, der zwischen 100 und 200 μm ausmacht, und eine Porentiefe (d), die zwischen 50 und 200 μm ausmacht, wobei der Abstand zwischen benachbarten Poren zwischen 50 und 200 μm liegt und wobei nahe an einem zumindestens wesentlichen Teil der Oberflächenporen zumindestens eine Erhöhung (3) liegt, die sich über die Oberfläche des Implantats erhebt und den Rand der Pore umgibt, dadurch gekennzeichnet, daß die größte Höhe (h) der Erhebung über der Materialoberfläche (4) mindestens 1 μm, aber nicht mehr als 20 μm ausmacht.

2. Implantat nach Anspruch 1, wobei die Erhebung oder die Erhebungen aus einem Grat oder aus Graten bestehen, die die Pore vollständig oder teilweise umgeben.

3. Implantat nach Anspruch 1 oder 2, wobei die maximale Höhe der Erhebung über die Implantatoberfläche (4) mindestens 5 μm beträgt.

4. Implantat nach einem der Ansprüche 1-3, wobei zumindestens der Teil der Implantatoberfläche, der den Teil (1) mit den Oberflächenporen umfaßt, aus einem Metall, einem Polymer oder aus einem zusammengesetzten Material besteht, das im wesentlichen aus einem Metall oder einem Polymer besteht.

5. Implantat nach einem der Ansprüche 1-3, wobei zumindestens der Teil des Implantats, der den Teil (1) mit den Oberflächenporen umfaßt, aus einer Keramik oder aus einem zusammengesetzten Material besteht, das im wesentlichen aus einem Keramikmaterial besteht.

6. Implantat nach einem der Ansprüchen 1-5, wobei sowohl die Oberflächenporen als auch die Erhebungen, die die Oberflächenporen vollständig oder teilweise umgeben, durch Laserbehandlung des Implantatmaterials hergestellt werden.

Revendications

1. Implant destiné à être fixé en contact avec un tissu osseux nouvellement formé, lequel implant est constitué au moins en partie d'un matériau dense possédant, au moins dans une partie (1) de sa surface, des pores de surface (2), qui couvrent 5-40 % de ladite partie de surface (1) et doivent constituer une surface de contact pour le tissu osseux nouvellement formé, lesdits pores possédant un diamètre (D) qui est compris entre 100 et 200 μm, et une profondeur (d) de pores comprise entre environ 50 et 200 μm, dans lequel la distance entre des pores adjacents est comprise entre 50 et 200 μm, et dans lequel, à proximité d'au moins une fraction importante desdits pores de surface, il est prévu au moins un bossage (3) qui s'étend au-dessus de la surface de l'implant entourant le bord du pore, caractérisé en ce que la hauteur maximale (h) du bossage au-dessus de la surface (4) du matériau est égale au moins à 1 μm mais n'est pas supérieure à 20 μm.

2. Implant selon la revendication 1, dans lequel le bossage ou les bossages sont constitués par une nervure ou des nervures entourant complètement ou partiellement le pore.

3. Implant selon la revendication 1 ou 2, dans lequel la hauteur maximale du passage au-dessus de la surface (4) de l'implant est égale à au moins 5 μm.

4. Implant selon l'une quelconque des revendications 1 à 3, dans lequel au moins une partie de la surface de l'implant, qui comprend la partie (1) possédant lesdits pores de surface, est réalisée en un métal, un polymère ou un matériau composite constitué essentiellement d'un métal ou d'un polymère.

5. Implant selon l'une quelconque des revendications 1 à 3, dans lequel au moins la partie de l'implant, qui comprend la partie (1) possédant lesdits pores de surface, est formée d'une céramique ou d'un matériau composite constitué essentiellement d'un matériau céramique.

6. Implant selon l'une quelconque des revendications 1 à 5, dans lequel les pores de surface ainsi que les bossages, qui entourent complètement ou partiellement les pores de surface, sont formés par traitement par laser du matériau d'implant.

Fig. 1

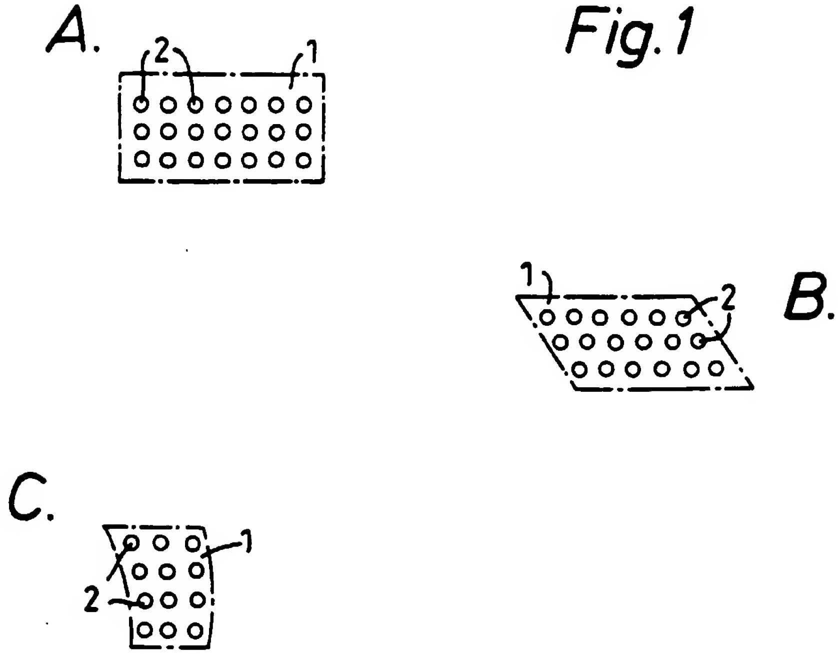

Fig. 2

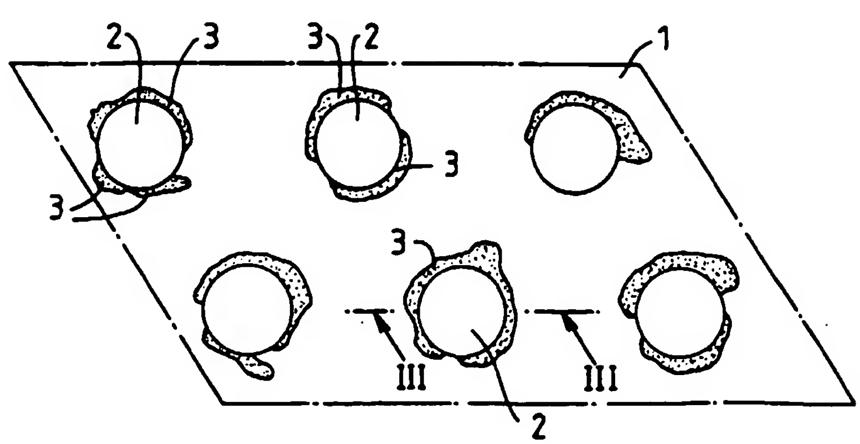

Fig. 3

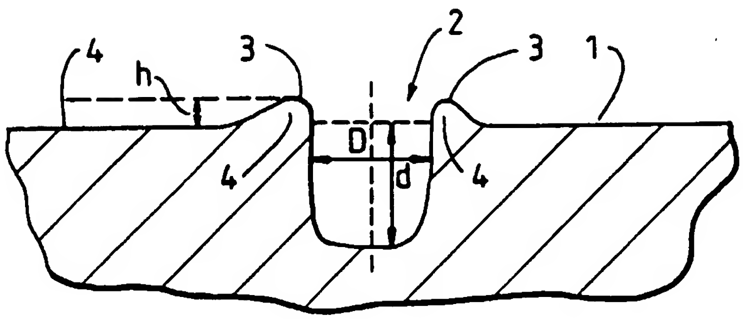

Fig. 4